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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/519,988	07/25/2005	Dieter Scharnweber	17P21PCT/US	3213
366/08 7590 12/15/2008 GUDRUN E. HUCKETT DRAUDT SCHUBERTSTR. 15A WUPPERTAL, 42289 GERMANY			EXAMINER KIM, YOUNG J	
			ART UNIT 1637	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/519,988

Applicant(s)

SCHARNWEBER ET AL.

Examiner

Young J. Kim

Art Unit

1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 October 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 23-44 is/are pending in the application.
- 4a) Of the above claim(s) 37-44 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 23-36 is/are rejected.
- 7) ☒ Claim(s) 30 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/CDC)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____
- Paper No(s)/Mail Date _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114 was filed in this application after appeal to the Board of Patent Appeals and Interferences, but prior to a decision on the appeal. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(c) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on October 23, 2008 has been entered.

Preliminary Remark

Claims 23-44 are pending.

Claims 37-44 are withdrawn from further consideration as being drawn to non-elected invention, non-elected with traverse in the Election received on August 3, 2007.

Lack of Unity of Invention

Applicants statement found on page 5, 4th paragraph is correct in that the invention of Group III is drawn to a method of "using" the product, and not making the product. Applicants state that as a result, Groups I-III are contain unity of invention in that they relate to a single category of invention - that is, a product, and a method of making and using the same.

While this criteria may be met, Applicants' are advised that the product elected for prosecution is neither novel nor unobvious over the prior art.

Therefore, the restriction is maintained and claims 37-44 are withdrawn.

Claim Objections

Claim 30 is objected to because of the following informalities: claim 30 recites the word, “desoxyribonucleic.” The word should be, “deoxyribonucleic.”

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 31 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 31 recites the phrase, “wherein the nucleic acid compounds have modifications of the sugar phosphate backbone caused by modifying agents, wherein the modifying agents are selected from the group consisting of phosphothioates, O-methyl groups, and unconventional bases.”

Claim 31 depends from claim 30.

Claim 30 already defines what the nucleic acid compounds are by limiting them to be from a Markush group consisting of DNA, RNA, PNA, LNA, and mixtures thereof. PNA and LNA already comprises modifications in the phosphate backbone (e.g., PNA having an amide linkage).

Therefore, it is unclear whether Applicants are stating that PNA further comprises phosphothioate or O-methyl modifications in addition to the amide modification.

Claim Rejections - 35 USC § 102

The rejection of claims 23-30, 32, 33, 35, and 36 under 35 U.S.C. 102(b) as being anticipated by Bitner, R.M. (EP 0 391 608 A2, published October 10, 1990), made in the Office Action mailed on March 4, 2008 is withdrawn in view of the Amendment received on October 23, 2008.

Claim Rejections - 35 USC § 103

The rejection of claim 31 under 35 U.S.C. 103(a) as being unpatentable over Bitner, R.M. (EP 0 391 608 A2, published October 10, 1990) in view of Wengel et al. (U.S. Patent No. 6,670,461, issued December 30, 2003, filed on May 9, 2001), made in the Office Action mailed on March 4, 2008 is withdrawn in view of the Amendment received on October 23, 2008.

The rejection of claim 34 under 35 U.S.C. 103(a) as being unpatentable over Bitner, R.M. (EP 0 391 608 A2, published October 10, 1990) in view of Yabusaki et al. (WO 85/02628, published June 20, 1985), made in the Office Action mailed on March 4, 2008 is withdrawn in view of the Amendment received on October 23, 2008.

Rejections, New Grounds

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 23-30, 32, and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Worch et al. (WO 98/17844, published April 30, 1998; herein, "Worch-1") as evidenced by Worch

et al. (U.S. Patent No. 6,524,718 B1, published February 25, 2003; herein, "Worch-2") in view of Bitner, RM (EP 0 391 608 A2, published October 10, 1990).

Preliminarily, Worch-2 is a national phase of the PCT/DE97/02465 application wherein Worch-1 is its WIPO publication.

Therefore, Worch-2 is used as an English translation of Worch-1.

Should Applicants traverse that Worch-2 is not a faithful translation of Worch-1's WIPO publication, Applicants are then: a) arguing that U.S. Patent 6,524,718 was not entitled to the National Phase filing date, of which the attorney of record had been prosecuting; or b) that National phase need not be the same document of its PCT counterpart, the argument of which would simply be erroneous.

In addition, the Office is requesting an English translation of Worch-1 to PTO's translation service concurrently at the time of the present Office communication.

All citations of the teachings of Worch-1 will be referred to those found in Worch-2 document.

Worch-1 discloses a metallic object comprising a coating that is comprised of a thin metal oxide layer (column 2, lines 22-24) and one other organic and/or inorganic component, wherein said organic component is explicitly disclosed as being biomolecules, and/or oligomers (column 2, lines 48-49), wherein said organic components can be incorporated into the metallic oxide phase such that it can "extend beyond the polyphase oxide (the metal oxide layer) coating (column 2, lines 55-59).

With regard to claim 27, the metal of the metallic object is a valve metal or its alloy (column 2, lines 25-31).

With regard to claim 28, the metal or metallic object is aluminum, titanium, tantalum, zirconium, niobium (column 2, lines 25-28).

With regard to claim 29, the alloy is an intermetallic phase (column 2, lines 26-27).

Worch-1, while explicitly teaching that biomolecules and oligomers can be bound, does not explicitly state that nucleic acid should be bound to the metallic object.

Worch-1 does not teach that nucleic acids are immobilized at their 3' or 5' terminal ends or that the unincorporated ends are freely accessible for subsequent interactions with other molecules (claim 24).

Worch-1 does not teach that the incorporated 5' terminal or 3' terminal ends have anionic groups (claim 25), and that said anionic groups is phosphate, phosphonate, or sulfonate (claim 26).

Worch-1 does not further define that the nucleic acid is DNA, RNA, PNA, LNA, or combination thereof (claim 30).

Worch-1 does not state that the nucleic acid comprises a modification to its backbone (claim 31).

Worch-1 does not the nucleic acids are present at least partially as individual strands (claim 32) and that said partially individual strands are bound to their complementary counterpart (claim 33), or that they are covalently bound (claim 34) and that the metallic object further comprises active ingredients (claim 36), wherein said ingredient comprises radioactive elements (claim 37).

Bitner also disclose a solid support comprising an amount of metal oxide (metallic object) comprising a coating that is comprised of a thin metal oxide layer (page 3, line 20; page 4, line 16; page 7, lines 15-16), and nucleic acid incorporated to said metal oxide layer (page 3, lines 22-23).

With regard to claims 24 and 33, the nucleic acids retain their biological accessibility and reactivity, such as for hybridization (page 5, lines 10-13).

With regard to claims 25 and 26, the artisans disclose that the phosphate backbone of DNA molecules play a significant role in the sorption of the DNA molecules (page 5, lines 32-33).

With regard to claims 30 and 32, the nucleic acid is single or double-stranded DNA or RNA or oligonucleotides (page 5, lines 29-30).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Worch-1 and Bitner, thereby arriving at the invention as claimed for the following reasons.

While Worch-1 did not explicitly point out that every possible oligomer be employed, the artisans had clearly contemplated those of the biological source, as they clearly and explicitly state that "biological materials" can be immobilized to their metallic object. Clearly, one of ordinary skill in the art, reading the disclosure would have recognized that when reading biological material together with the term, "oligomer" would had envisioned that such would include string of monomers such as amino acids or nucleotides.

And given the fact that the art of immobilizing nucleic acids on metal coated surfaces had already been practiced (as evidenced by Bitner) for the purpose of solid phase hybridization detection, one of ordinary skill in the art would have clearly been motivated and would have had a reasonable expectation of success at applying the teachings of Worch-1 for the purpose of generating a metal coated object comprising nucleic acid thereon.

In *KSR International Co. v. Teleflex Inc.* (550 U.S. ___, 82 USPQ2d 1385 (2007); herein, *KSR*), the Supreme court reaffirmed the familiar framework for determining obviousness as set forth in *Graham v. John Deere Co.* (383 U.S. 1, 148 USPQ 459 (1966)), but stated that the Federal Circuit had erred by applying the teaching-suggestion-motivation (TSM) test in an overly rigid and formalistic way. *KSR*, 550 U.S. at ___, 82 USPQ2d at 1391.

Specifically, the Supreme Court stated that the **Federal Circuit had erred in four ways:** (1) “by holding that courts and patent examiners should look only to the problem the patentee was trying to solve” (Id. at ___, 82 USPQ2d at 1397); (2) by assuming “that a person of ordinary skill attempting to solve a problem will be led only to those elements of prior art designed to solve the same problem” (Id.); (3) **by concluding “that a patent claim cannot be proved obvious merely by showing that the combination of elements was obvious to try”** (Id.); **and** (4) **by overemphasizing “the risk of courts and patent examiners falling prey to hindsight bias” and as a result applying “[r]igid preventative rules that deny factfinders recourse to common sense”** (Id.). In KSR, the Supreme Court particularly emphasized “the need for caution in granting a patent based on the combination of elements found in the prior art,” Id. at ___, 82 USPQ2d at 1395, and discussed circumstances in which a patent might be determined to be obvious. Importantly, the **Supreme Court reaffirmed** principles based on its precedent that **“[t]he combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results.”** Id. at ___, 82 USPQ2d at 1395.

The art of immobilizing nucleic acids in metal oxide coating had already been known in the prior art (as evidenced by Bitner), and given the fact that Worch-1 contemplates immobilization of biological molecules as well as their oligomers, one of ordinary skill in the art at the time the invention was made would have reasonably concluded that immobilization of nucleic acids onto the metal coated substrate of Worch-1 would have yielded no more than a predictable result, rendering the invention as claimed *prima facie* obvious over the cited references.

Claim 31 is rejected under 35 U.S.C. 103(a) as being unpatentable over Worch et al. (WO 98/17844, published April 30, 1998; herein, “Worch-1”) as evidenced by Worch et al. (U.S. Patent

No. 6,524,718 B1, published February 25, 2003; herein, "Worch-2") in view of Bitner, RM (EP 0 391 608 A2, published October 10, 1990), as applied to claims 23-30, 32, and 33 above, and further in view of Wengel et al. (U.S. Patent No. 6,670,461, issued December 30, 2003, filed May 9, 2001).

The teachings of Worch-1 and Bitner have already been discussed above.

Neither of the artisans discloses the use of nucleic acid compounds that have modifications made thereto.

Wengel et al. disclose locked nucleic acids (LNA) used in a diagnostic assay for detecting target nucleic acid with LNA probes via hybridization (column 2, lines 42-52).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Worch-1 and Bitner with the teachings of Wengel et al., thereby arriving at the invention as claimed for the following reasons.

While Worch-1 nor Bitner explicitly disclose the use of other forms of nucleotide analogs, which could be used as probes, one of ordinary skill in the art at the time the invention was made would have recognized that the advantage offered by LNA would have benefited said one of ordinary skill in the art to allow more stringent hybridization conditions, so as to preclude false positives in a hybridization assay provided for by Bitner. The desire to increase stringency, as evidenced by Wengel et al., has been well-established in the art of nucleic acid hybridization detection. Hence, one of ordinary skill in the art would have been motivated to employ LNA nucleotide analogs into the immobilized nucleic acids of Bitner, thereby arriving at the invention as claimed.

Therefore, the invention as claimed is deemed *prima facie* obvious over the cited references.

Claims 34-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Worch et al. (WO 98/17844, published April 30, 1998; herein, "Worch-1") as evidenced by Worch et al. (U.S. Patent No. 6,524,718 B1, published February 25, 2003; herein, "Worch-2") in view of Bitner, RM (EP 0 391 608 A2, published October 10, 1990), as applied to claims 23-30, 32, and 33 above, and further in view of Yabusaki et al. (WO 85/02628, published June 20, 1985).

The teachings of Worch-1 and Bitner have already been discussed above.

Neither of the artisans discloses that the hybridized nucleic acids are covalently bonded to the immobilized nucleic acids.

With regard to claims 35 and 36, Bitner discloses the labeling of the hybridized DNA molecules (page 8, lines 30-41; page 10, line 57).

Yabusaki et al. disclose a method of forming covalent bonds between two hybridized nucleic acids by employing a nucleic acid with comprises cross-linking molecules that is covalently incorporated (page 3, lines 28-31; Abstract; page 32, lines 13-15).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to employ the teachings of Worch-1 and Bitner with the teachings of Yabusaki et al., thereby arriving at the invention as claimed for the following reasons.

One of ordinary skill in the art, at the time the invention was made would have recognized that the formation of covalent bonds between the two hybridized nucleic acids would have allowed for stringent wash conditions so as to minimize false positive results in their hybridization assay, by forming a covalent bond between the immobilized nucleic acid and the hybridized nucleic acid of Worch-1 and Bitner, thereby arriving at the claimed invention.

One of ordinary skill in the art at the time the invention was made would have had a reasonable expectation of success at combining the teachings, given the fact that Yabusaki et al.

employs the formation of covalent bonds between a probe and a target nucleic acid for the purpose of detection, demonstrating that cross-linking (for the formation of covalent bonds) could be made in solution, the conditions of which is also used by Bitner.

Therefore, the invention as claimed is deemed *prima facie* obvious over the cited references.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

The rejection of claims 23-36 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-9 of U.S. Patent No. 6,524,718 (herein ‘718 patent), made in the Office Action mailed on March 4, 2008 is maintained for the reasons already of record.

Applicants’ arguments presented in the Amendment received on October 23, 2008 have been fully considered but they are not found persuasive for the reasons set forth in the, “Response to Arguments” section.

The Rejection:

Although the conflicting claims are not identical, they are not patentably distinct from each other for the following reasons.

Claim 1-9 of the '718 patent is drawn to a metallic object consisting of a valve metal or valve metal alloy and a thin polyphase oxide coating comprising a metal oxide phase and a second phase, wherein said second phase is selected from biomolecules, such as oligomers (claim 2).

Therefore, the claims of the '718 patent renders the claims of the instant application obvious.

Response to Arguments:

Applicants arguments regarding ODP when claimed subject matter claimed in a commonly owned patent, or a non-commonly owned patent but subject to joint research agreement is subject to ODP.

This argument is not found persuasive because the MPEP states that when two application having at least one inventor in common has at least one conflicting claim, ODP is necessary.

Conclusion

No claims are allowed.

Inquiries

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Young J. Kim whose telephone number is (571) 272-0785. The Examiner is on flex-time schedule and can best be reached from 9:00 a.m. to 5:30 p.m (M-F). The Examiner can also be reached via e-mail to Young.Kim@uspto.gov. However, the office cannot guarantee security through the e-mail system nor should official papers be transmitted through this route.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. Gary Benzion, can be reached at (571) 272-0782.

Papers related to this application may be submitted to Art Unit 1637 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official

Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If applicant does submit a paper by FAX, the original copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office. All official documents must be sent to the Official Tech Center Fax number: (571) 273-8300. For Unofficial documents, faxes can be sent directly to the Examiner at (571) 273-0785. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Young J. Kim/
Primary Examiner
Art Unit 1637
12/15/2008

/YJK/